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Application Number	09/852,966-Conf. #5588
Filing Date	May 10, 2001
First Named Inventor	Rima KADDURAH-DAOUK
Art Unit	1618
Examiner Name	M. G. Hartley
Attorney Docket Number	AVZ-020CNRCE

ENCLOSURES (*Check all that apply*)

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  - [ ] After Final
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Remarks

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Firm Name	LAHIVE & COCKFIELD, LLP		
Signature	Cynthia Soroos		
Printed name	Cynthia M. Soroos		
Date	September 2, 2008	Reg. No.	53,623

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Docket No.: AVZ-020CNRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Rima Kaddurah-Daouk

Application No.: 09/852,966 Confirmation No.: 5588

Filed: May 10, 2001 Art Unit: 1618

For: USE OF CREATINE OR CREATINE COMPOUNDS FOR SKIN PRESERVATION Examiner: M. G. Hartley

AMENDMENT AND RESPONSE TO DECISION ON APPEAL

MS Board of Patent Appeals and Interference
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Decision on Appeal mailed from the U.S. Patent and Trademark Office in connection with the above-identified application on July 1, 2008. No extension of time is required.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions of the claims and listing of the claims in the application:

Claims 1- 67 **(Cancelled)**

68. **(Currently Amended)** A method for increasing energy reserves in the skin of a subject, comprising administering to said subject an effective amount of creatine or a salt thereof and a skin preserving agent, such that the energy reserves in the skin of said subject is increased, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue, wherein said skin preserving agent is selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide.

69. **(Currently Amended)** A method for sustaining energy production in the skin of a subject, comprising administering to said subject an effective amount of creatine or a salt thereof and a skin preserving agent, such that energy production the skin of said subject is sustained, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue, wherein said skin preserving agent is selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide.

70. **(Currently Amended)** A method for modulating energy flow in the skin of a subject, comprising administering to said subject an effective amount of creatine or a salt thereof and a skin preserving agent, such that the energy flow in the skin of said subject is modulated, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue, wherein said skin preserving agent is selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide.

71. **(Cancelled)**

72. **(Previously Presented)** The method of claim 68, 69, or 70, wherein said creatine salt is creatine monohydrate.

73. **(Previously Presented)** The method of claim 68, 69, or 70, wherein said creatine salt is creatine citrate.

74.-81. **(Cancelled)**

82. **(Previously Presented)** The method of any one of claims 68-70, further comprising the coadministration of a sunscreen or sunblock.

83. **(Previously Presented)** The method of claim 82, wherein said sunscreen or sunblock is zinc oxide or titanium dioxide.

84. **(Previously Presented)** The method of any one of claims 68-70, further comprising the coadministration of a pharmaceutical carrier suitable for topical administration.

85. **(Previously Presented)** The method of any one of claims 68-70, wherein said subject is a human.

86. **(Cancelled)**

87. **(Cancelled)**

88. **(Previously Presented)** The method of claim 68, 69, or 70, wherein said skin disorder is skin wrinkles.

89. **(New)** The method of claim 68, wherein said creatine salt is creatine ascorbate.

90. **(New)** The method of claim 69, wherein said creatine salt is creatine ascorbate.

91. **(New)** The method of claim 70, wherein said creatine salt is creatine ascorbate.

92. **(New)** The method of claim 68, wherein said creatine salt is creatine ascorbate and said skin preserving agent is ethylenediamine tetraacetic acid (EDTA).

93. **(New)** The method of claim 70, wherein said creatine salt is creatine ascorbate and said skin preserving agent is ethylenediamine tetraacetic acid (EDTA).

94. **(New)** The method of claim 71, wherein said creatine salt is creatine ascorbate and said skin preserving agent is ethylenediamine tetraacetic acid (EDTA).

REMARKS

Claims 68-70, 72, 73, 75-85 and 88 were pending in the application. Claims 68-70 have been amended, claims 75-81 have been cancelled without prejudice and new claims 89-94 have been amended. Therefore, upon entry of this paper, claims 68-70, 72, 73, 82-85 and 88-94 will be pending.

No new matter has been added. Support for the amendments to claims 68-70 may be found, for example, at least at page 17, line 36 through page 18, line 8 of the specification as originally filed. Support for new claims 89-91 may be found, for example, at least at page 23, lines 35-36 of the specification as originally filed. Support for new claims 92-94 may be found, for example, at least at page 18, line 4 and at page 23, lines 35-36 of the specification as originally filed.

The foregoing claim cancellations and amendments should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejection, and have been made solely to expedite prosecution of the present application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application.

Rejection of Claims 68-70 under 35 U.S.C. §102(b)

Claims 68-70 are rejected under 35 U.S.C. §102(b) as being anticipated by Yu *et al.* (U.S. Patent No. 5,702,688). Specifically, the Board of Patent Appeals and Interferences (hereinafter "the Board") asserts that "Yu discloses a method having all of the instantly claimed method steps of claims 68-70 (*i.e.*, administering creatine to a subject having a skin disorder associated with aging)" and that "the treatment taught by Yu would inherently cause the same results as the claimed method." Applicants respectfully traverse for at least the following reasons.

As amended, claims 68-70 are directed to methods for increasing, sustaining and modulating energy reserves in the skin of a subject by administering to the subject an effective amount of ***creatine*** or a salt thereof ***and a skin preserving agent,*** in which the skin preserving agent is selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide.

In contrast, Yu *et al.* discloses compositions and methods for treating skin disorders using an amphoteric composition comprising an amphoteric compound and at least one of an alpha hydroxyacid or an alpha ketoacid, and where the amphoteric compound may be creatine. However, Yu *et al.* fails to teach or suggest the use of ***creatine or a salt thereof and and a skin***

preserving agent selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide for increasing, sustaining or modulating energy reserves in the skin of a subject. Accordingly, the methods disclosed by Yu *et al.* fail to meet all of the limitations of claims 68-70 and therefore, claims 68-70 are not anticipated by Yu *et al.*

Based at least on the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection uner 35 U.S.C. §102(b).

Rejection of Claims 68-70 under 35 U.S.C. §102(b)

Claims 68-70 are rejected under 35 U.S.C. §102(b) as being anticipated by Kaddurah-Daouk *et al.* (International Application Publication No. WO 96/14063). Specifically, the Board asserts that "Kaddurah-Daouk '063 discloses the instantly claimed method steps of administering creatine to an aging person; *i.e.*, a subject suffering from a skin disorder associated with aging." Applicants respectfully traverse for at least the following reasons.

As described above, claims 68-70 are directed to methods for increasing, sustaining and modulating energy reserves in the skin of a subject by administering to the subject an effective amount of ***creatine*** or a salt thereof ***and a skin preserving agent,*** in which the skin preserving agent is selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide.

In contrast, Kaddurah-Daouk *et al.* discloses methods of treating diseases of the nervous system (*e.g.*, Alzheimer's disease, Parkinson's disease, Huntington's disease and the like) in a subject by administering to the subject an amount of one or more compounds (*e.g.*, creatine, phosphocreatine or analogs thereof) which modulate one or more of the structural or functional components of the creatine kinase/phosphocreatine system (*e.g.*, creatine, creatine phosphate, creatine kinase and transporter of creatine) sufficient to prevent, reduce or ameliorate the symptoms of the disease. However, Kaddurah-Daouk *et al.* fails to teach or suggest the use of an effective amount of ***creatine*** or a salt thereof ***and a skin preserving agent,*** in which the skin preserving agent is selected from the group consisting of coenzyme Q10 (CoQ10), sodium bisulfate, sodium metabisulfite, sodium sulfite, ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ethylenediamine tetraacetic acid (EDTA), sorbitol, phosphoric acid, ATP and nicotinamide for increasing, sustaining or modulating energy reserves in the skin of a subject. Accordingly, the methods disclosed by Kaddurah-Daouk *et al.* fail to

meet all of the limitations of claims 68-70 and therefore, claims 68-70 are not anticipated by Kaddurah-Daouk *et al.*

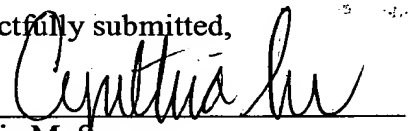
Based at least on the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b).

SUMMARY

In view of the foregoing remarks, reconsideration and withdrawal of all rejections and allowance of the instant application with all pending claims are respectfully solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Dated: September 2, 2008

Respectfully submitted,

By 

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